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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,694	12/28/2001	Steven D. Kruse	1416.49US01	2324

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EXAMINER

SWEET, THOMAS.

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,694

Applicant(s)

KRUSE ET AL.

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-21, 23-26 and 29 is/are rejected.
- 7) ☒ Claim(s) 16-18, 22, 27 and 28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: ____

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DETAILED ACTION

Drawings

New corrected drawings are required in this application because they are informal. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation "the commissure posts" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-4, 6-7, 9-10, 14-15, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al (US 5899937). Goldstein et al discloses test apparatus and method for testing a stented heart valve with a flexible membrane (fig. 2) by applying backwards pressure (Col 10, lines 44-47) to the valves in the flow blocking position. Based of figure 2 the valve does not open fully in the forward flow direction more than about 80% of the cross sectional area. The test apparatus (fig. 3) comprises a cyclic pressure applicator (pump chamber) a conduit connected to the pressure applicator and a stent test structure mounted in the conduit (fig. 2).

With regard to claim 4, Column 10, lines 44-47 states that the peak pressure would be 120 mm Hg.

With regard to claim 14, see the abstract.

Claim 29 is rejected under 35 U.S.C. 102(e) as being anticipated by Cai et al (US 6562069).

The applied reference has a common Assignee and two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 11-13, 19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al in view of Pietsch et al (US 4778461). Goldstein et al discloses a test apparatus and method for testing a stented heart valve as discussed above. However, Goldstein et al remains silent as to the heart valve stent having commissure posts and does not disclose the heart valve membrane being made of polyurethane or silicone integrally cast with the stent. Heart valves having commissure posts and having a membrane of polyurethane or silicone integrally cast with the stent are well known in the art of heart valves as demonstrated by Pietsch et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to test the stent of Pietsch et al in the test apparatus of Goldstein et al in order to perform tests on the valve of Pietsch et al.

With regard to claim 5, the commissure post would inherently deflect inward the equivalent amount that they would when subject to a pulse duplicator at physiological condition, since the test apparatus functions at physiological condition.

Claims 8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al in view of Eberhardt (US 5176153). Goldstein et al discloses a test apparatus and method for testing a stented heart valve as discussed above. However, Goldstein et al does not disclose testing at a frequency of from about 1000 to about 6000 cycles per minute. Eberhardt

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teaches another a test apparatus and method for testing a stented heart valve which includes testing at a frequency of up to 400 cycles per second (Col 6 lines 29-43, i.e. up to 24000 cycles per minute) for the purpose of accelerated wear and fatigue testing. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the test apparatus of Goldstein et al in order to test at a frequency of up to 24000 cycles per minute (including 1000-6000 cycles per minute) as taught by Eberhardt in order to perform accelerated wear and fatigue tests.

Allowable Subject Matter

Claims 16-18, 22 and 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vilendrer, Kent (US 5,670,708), Nguyen et al. (US 5,272,909), Eberhardt et al. (US 5,406,857), and More et al. (US 5,531,094).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018. The examiner can normally be reached on 6:30 am - 5:00pm M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.

tjs
July 7, 2003

C2
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